IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

)
UNITED STATES OF AMERICA,)
Plaintiff,) Civil Action No. 5:22-cv-05055-JFM
v.)
INHANCE TECHNOLOGIES LLC,) ORAL HEARING SCHEDULED FOR 8/23/23
Defendant.))
	ORAL HEARING SCHEDULI FOR 8/23/23)

INHANCE TECHNOLOGIES LLC'S OPPOSITION TO INTERVENOR-PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Intervenors urge this Court to re-tool the requirements for Article III standing, the standard for summary judgment, and the scope of a court's equitable discretion in their quest to short-circuit this case. But Intervenors' arguments range from vague to unproven to facially inaccurate. This Court should decline to grant their request for injunctive relief.

To start, Intervenors have failed to clear Article III's requirements of an injury-in-fact, fairly traceable to the defendant's challenged conduct. Instead, Intervenors rely on vague speculation about the possible risks of exposure to PFAS in plastic containers, a purported "injury" that is (a) not cognizable under Supreme Court precedent, and (b) entirely unrelated to whether or not Inhance properly submitted a Significant New Use Notice to EPA.

Even if Intervenors had standing to sue, their arguments suffer from much the same failures as the Government's request for summary judgment. Intervenors seek relief based on critical factual issues before EPA has issued a decision on Inhance's fluorination technology, before discovery has occurred in this case, and before a factual record exists. Indeed, Intervenors exacerbate the Government's errors by doubling down on purportedly "uncontested" assertions that are in reality genuinely disputed issues of material fact, and supplementing their brief with unverified, independent studies that have not been vetted through discovery or the expert process.

Finally, Intervenors attempt to strip this Court of its equitable authority, arguing that an injunction is mandatory in the event of a finding of liability. But neither Supreme Court precedent nor the Toxic Substances Control Act mandates an injunction issue, particularly at this early stage of litigation. In fact, the equities cut the other way: Abruptly requiring Inhance to cease its fluorination technology would massively disrupt a variety of industries, and would cause irreparable harm to Inhance itself.

FACTUAL BACKGROUND

Inhance provides "barrier protection" and other surface fluorination technologies that transform customers' conventional plastics into high-performance materials. Iyer Decl. ¶ 5.

Inhance's fluorination technology treats plastic articles, including high-density polyethylene (HDPE) containers and fuel tanks. Iyer Decl. ¶ 13; Ex. 12. During this fluorination, these plastic articles are placed in one of Inhance's fluorination chambers and exposed to fluorine and inert gas under specified parameters. Iyer Decl. ¶ 13; Ex. 16. Plastic articles, like those fluorinated by Inhance, are not chemical substances or mixtures. Therefore, any long-chain perfluoroalkyl carboxylate (LCPFAC) are produced during the treatment of an article. Iyer Decl. ¶ 20; Ex. 4. Any LCPFACs that may be unintentionally formed during fluorination cannot be separated from the fluorinated article during the fluorination process. *Id*.

Inhance has been using its current technology for fluorinating fuel tanks, fuel storage containers, and HDPE plastic containers for over four decades. Iyer Decl. ¶ 8. Inhance—formerly Fluoro-Seal International—began fluorinating in 1983. Today, Inhance has 10 facilities across the United States that provide fluorination services for plastic containers and fuel tanks. Iyer Decl. ¶ 9; Ex. 16. Apart from parameter enhancements that *reduce* the potential for the formation of LCPFACs, the fluorination process has not changed in any material way since 1983. *Id.* EPA visited Inhance's West Chicago facility in 2014 and inspected the fluorination process. *See* Iyer Decl. ¶ 27. EPA raised no concerns about generation of LCPFACs at the facility following the visit. *Id.*

In 2015, EPA began its rulemaking process for the Significant New Use Rule (SNUR), which was finalized in July 2020. *See* 85 Fed. Reg. 45109, 45116 (July 27, 2020). Although EPA specifically identified a number of manufacturing processes as targeted by the new rule during the

five-year rulemaking, EPA did not identify fluorination of containers as a targeted use, in either the proposed rule or the final rule. Exs. 5, 7. Inhance continued to operate for over 18 months following publication of the Final Rule, with no objection by EPA. *See* Iyer Decl. ¶ 36.

Then, in January 2021, EPA issued a subpoena seeking information related to Inhance's fluorination processes, to which Inhance promptly responded. Iyer Decl. ¶ 37; Ex. 17. EPA issued supplemental information requests seeking additional information from Inhance through the end of 2022. Iyer Decl. ¶ 37.

In March 2022, EPA's enforcement office sent a Notice of Violation (NOV) to Inhance, alleging for the first time that Inhance's fluorination technology produces LCPFACs and is therefore subject to the SNUR. Iyer Decl. ¶ 35; Ex. 18 (Notice of Violation Letter). Two weeks later, EPA's enforcement office issued an open letter to industry, asserting for the first time publicly that the rule applied to the fluorination industry. Iyer Decl. ¶ 38; Ex. 19 (Letter from Dr. Tala R. Henry, Deputy Director, Office of Pollution Prevention & Toxics (Mar. 16, 2022)). Inhance continued to provide additional information to the agency through February 2023. Iyer Decl. ¶ 37.

Although Inhance has consistently maintained that TSCA does not require Significant New Use Notices (SNUNs) for its particular use, Inhance submitted SNUNs to EPA under protest in November 19, 2022 and December 6, 2022. Gov. SUMF ¶ 17; Iyer Decl. ¶ 39; Exs. 3, 4. On December 30, 2022, Inhance resubmitted the SNUNs to EPA consistent with instructions provided by the agency. See Iyer Decl. ¶ 40; Ex. 8 (Certain New Chemicals; Receipt and Status Information for January 2023, 88 Fed. Reg. 10320, 10323-24 (Feb. 17, 2023)). In both notices, Inhance preserved its position that Inhance's fluorination technology is not subject to the SNUR. Specifically, Inhance stated in the notices: "The Company is submitting the SNUNs to address

allegations of noncompliance with the LCPFACs SNUR made by EPA. The SNUNs are neither an admission of fact nor agreement that the SNUR is legally applicable to the Company's fluorination of HDPE containers." Ex. 3 (Preliminary Statement).

The agency has not yet completed its administrative review of the information Inhance submitted to the agency. *Id.* EPA's administrative process will assess the risk, if any, posed to the environment and human health by Inhance's fluorination technology. At the conclusion of its review, EPA may conclude "that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(a)(3)(A). Alternatively, the agency may conclude the substance or significant new use "is not likely to present an unreasonable risk of injury to health or the environment." § 2604(a)(3)(C). And finally, should EPA conclude that the available information is "insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use," § 2604(a)(3)(B)(i)—or if "in the absence of sufficient information to permit the Administrator to make such an evaluation," EPA believes the substance "may present an unreasonable risk of injury to health or the environment," § 2604(a)(3)(B)(ii)(I)—the Administrator may take steps to "prohibit or limit" certain activities by the substance's manufacturer "to the extent necessary to protect against an unreasonable risk of injury to health or the environment," § 2604(e)(1)(A).

PROCEDURAL BACKGROUND

The Department of Justice initiated an action against Inhance in this Court on December 19, 2022, while EPA's administrative process was still under way, seeking declaratory and injunctive relief for purported violations of TSCA. ECF No. 3. Eight days later, Intervenors Public Employees for Environmental Responsibility (PEER) and Center for Environmental Health (CEH) (collectively, the "Organizations") filed a nearly identical lawsuit in the United States District

Court for the District of Columbia. *Center for Env't. Health v. Inhance Techs. USA*, No. 22-3819 (D.D.C. Dec. 27, 2022). One month after their lawsuit was filed, Intervenors modified their Complaint to add Jay De La Rosa as a Plaintiff. *Center for Env't. Health v. Inhance Techs. USA*, No. 22-3819, ECF No. 12.

In February 2023, Inhance moved to dismiss the Intervenors' D.D.C. Complaint, explaining that the "diligent prosecution" bar in Section 20(a) of the Toxic Substances Control Act (TSCA) precluded their separate action. Also in February 2023, Inhance moved to dismiss the Government's parallel complaint on the same latter grounds: lack of ripeness, and a "New Use" cannot embrace an old one. ECF Nos. 10, 40. That motion remains pending.

In April 2023, the District of Columbia district court dismissed Intervenors' lawsuit based on TSCA's "diligent prosecution" bar. *Center for Env't. Health v. Inhance Techs. USA*, No. CV 22-3819, 2023 WL 2808710 (D.D.C. April 6, 2023). In so doing, the district court explained that "Plaintiffs' proper recourse is to seek to intervene" in the government's parallel case before this Court. *Id.* at *4. Plaintiffs subsequently sought and received leave to intervene in this matter in late April. *Center for Env't. Health v. Inhance Techs. USA*, No. 22-3819, ECF Nos. 30, 33.

On May 16, 2023, the Government moved for partial summary judgment on its claim for declaratory relief (but not on its claim for injunctive relief). ECF No. 37. Nearly a month later, on June 12, 2023—after this Court had set the briefing schedule for that and other pending motions, with Intervenors' participation—Intervenors moved for summary judgment on their claims for both declaratory and injunctive relief.

Discovery has not yet started in this case.

STANDARD OF REVIEW

Summary judgment is proper only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is "genuine" if there is evidence from which a reasonable factfinder could find for the non-moving party, and a dispute is "material" if it might affect the outcome of the case under governing law. *Kaucher v. County of Bucks*, 455 F.3d 418, 423 (3d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The court views the evidence in the light most favorable to the non-moving party. *Galena v. Leone*, 638 F.3d 186, 196 (3d Cir. 2011).

"[S]ummary judgment is improper so long as the dispute over the material facts is genuine." *Orsatti v. New Jersey State Police*, 71 F.3d 480, 482 (3d Cir. 1995). And when the non-movant shows that its opposition depends on information absent from the record before the court, Rule 56(d) requires that summary judgment "be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." *Liberty Lobby, Inc.*, 477 at 250 n.5.

ARGUMENT

Inhance incorporates by reference the arguments advanced in its opposition to the Government's motion for summary judgment, including the exhibits referenced therein. Inhance further opposes Intervenors' motion for summary judgment for the reasons that follow.

I. INTERVENOR-PLAINTIFFS LACK STANDING

The "irreducible constitutional minimum of standing" must be satisfied in order for a plaintiff to bring an action in federal court. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). And even where Congress has created a legal cause of action, "it may not simply enact an injury into existence." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2205 (2021). Rather, to

establish Article III standing, a plaintiff must demonstrate (1) an injury in fact, (2) a sufficient causal connection between the injury and the conduct complained of, and (3) a likelihood that the injury will be redressed by a favorable decision. *Lujan*, 504 U.S. at 560–561. "The party invoking federal jurisdiction bears the burden of establishing these elements, and, on summary judgment, the plaintiff cannot rely on mere allegations but must set forth ... specific facts demonstrating that these requirements have been met." *Freeman v. Corzine*, 629 F.3d 146, 153 (3d Cir. 2010) (quoting *Joint Stock Soc'y v. UDV N. Am., Inc.*, 266 F.3d 164, 175 (3d Cir. 2001)). "[P]laintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *TransUnion*, 141 S. Ct. at 2208. These Plaintiffs have failed to do so.

A. Intervenor De La Rosa Has Not Suffered Any Injury Fairly Traceable To Inhance's Challenged Actions.

Intervenor De La Rosa does not have Article III standing. First, Mr. De La Rosa has failed to demonstrate an "actual or imminent" injury. He has provided no facts that satisfy the Supreme Court's test, which requires that an injury "affect the plaintiff in a personal and individual way." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339 (2016).

Here, Mr. De La Rosa has not presented any evidence that he was (1) exposed to LCPFACs, (2) that any such exposure was the result of his handling of a fluorinated container, (3) that any such container was fluorinated by Inhance, or (4) that any such exposure to LCPFACs resulted in an injury. Instead, Mr. De La Rosa contends that he has come into contact with "potentially fluorinated plastic containers" and that he has experienced "fear and anxiety surrounding his own health and wellbeing." Intervenors' SJ Mem. 8, 10 (emphasis added); see also De La Rosa Decl. ¶ 8. And yet he admits that he continues to use plastic containers for a variety of activities, including recreational ones. De La Rosa Decl. ¶ 8. Mr. De La Rosa's "generalized anxieties" about the possibility of perhaps having encountered a container that perhaps might have been

fluorinated by Inhance—particularly when coupled with his continued, voluntary engagement with the purported source of that anxiety—is insufficient to show an injury in fact. *See Sierra Club v. GenOn Power Midwest LP*, No. 2:19-CV-1284, 2021 WL 4171748, at *5 (W.D. Pa. Sept. 14, 2021) (finding no concrete injury where Plaintiff "continues to use the area and has no plans to curb his use . . . [his] generalized anxieties over GenOn's discharges do not establish an injury in fact"); *Buckley v. Early Warning Servs., LLC.*, No. CV 20-5265, 2021 WL 5413887, at *1 (E.D. Pa. Sept. 28, 2021) ("Plaintiff alleges he suffers from potential exposure of future harm as well as emotional distress, but that is not enough because speculation does not constitute material harm. Thus, Plaintiff has not suffered a concrete harm and lacks standing.").

Nor has Mr. De La Rosa shown that any potential injury due to any PFAS exposure is "imminent." "Although imminence is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). The Supreme Court has "repeatedly reiterated that 'threatened injury must be *certainly impending* to constitute injury in fact,' and that '[a]llegations of *possible* future injury' are not sufficient." *Id.* (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). The D.C. Circuit in particular has expressed extreme skepticism that mere exposure is enough to satisfy Article III. *Public Citizen, Inc. v. National Highway Traffic Safety Admin.*, 489 F.3d 1279, 1295 (D.C. Cir. 2005) (requiring "substantially increased risk" and "substantial probability of harm with that increase taken into account"). Though it "has not closed the door to all increased-risk-of-harm cases, the door remains only slightly ajar." *Association of Am. Physicians & Surgeons, Inc. v. FDA*, 539 F. Supp. 2d 4 (D.D.C. 2008). While the Third Circuit has not yet expressly adopted the D.C. Circuit's reasoning, its cautionary approach is warranted here.

Mr. De La Rosa has also failed to demonstrate that his purported exposure to harm is "fairly traceable" to Inhance. *See Clapper*, 568 U.S. at 411. In his declaration, Mr. De La Rosa states only that it is "possible" that "the plastic containers [he] use[s] ...have been fluorinated" but that "he do[es] not know" either way. De La Rosa Decl. ¶ 6 (emphasis added). Noticeably absent from Mr. De La Rosa's declaration are any claims this his "fear and anxiety" stem from any potential PFAS generated by the Inhance fluorination process, as opposed to (a) the fluorination process of another company; (b) the manufacture of the containers themselves; or (c) the materials stored in the containers. Rather, Mr. De La Rosa's generalized concern is that he "may be exposed to [LCPFAC] chemicals" that may be present in plastic containers, that may (or may not) have been fluorinated by Inhance, in a manner that may (or may not) violate TSCA. Intervenors' SJ Mem.

8. That chain of speculation, underscored by Plaintiff's admitted uncertainty regarding Inhance's involvement, cannot serve as the basis for standing. *See Lujan*, 504 U.S. at 567 (standing may not be rooted in mere "speculation and fantasy").

Finally, Mr. De La Rosa has not established that his fear and anxiety are redressable by the Court. To satisfy the redressability requirement, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.' " *Lujan*, 504 U.S. at 561 (quoting *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976)). Mr. De La Rosa has presented no evidence that his "fear" and "anxiety" will subside if Inhance were enjoined from fluorinating containers. In fact, it is clear from Mr. De La Rosa's declaration that he has very little information on the plastic containers he uses, and that this lack of information is primarily driving his generalized concerns. De La Rosa Decl. ¶¶ 6, 8. Indeed, Mr. De La Rosa makes as much plain in his declaration, stating that he could obtain relief if there were to be a blanket "ban" on fluorinated containers or a "shift to fluorinated packaging that does not contain PFAS." *Id.* at ¶ 9.

He also alleges that he would obtain relief if "the labels of plastic containers were to disclose whether they have been fluorinated and contain PFAS." *Id.* But these grievances are properly directed towards Congress and EPA, not this Court. Even if this Court were to grant Mr. De La Rosa relief, none of these remedies would be available under TSCA. *See, e.g.*, 15 U.S.C. § 2616 (describing remedies available in enforcement lawsuit); § 2619 (describing scope of relief in civil actions brought by citizens). As such, a judgment directed against Inhance would do little to rectify Mr. De La Rosa's concerns. And in any event, an "informational injury that causes no adverse effects cannot satisfy Article III." *TransUnion*, 141 S. Ct. at 2214. *See also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court.").

Because Mr. De La Rosa has failed to establish the "irreducible constitutional minimum of standing," the Court should deny his Motion for Summary Judgment and dismiss his Complaint for lack of standing. *See Lujan*, 504 U.S. at 560.

B. The Organizations Lack Standing.

The Organizations also lack standing. Specifically, both Organizations have failed to establish that they have associational standing to pursue the claims espoused in the Complaint because they have failed to demonstrate that any member has standing to sue. And while neither Organization alleges organizational standing, that pathway is unavailable as well, because by their own admissions they have not diverted any unexpected resources toward addressing the issues raised in the Complaint.

1. The Organizations fail to establish associational standing.

To have associational standing, an organization must show that: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires

the participation in the lawsuit of each of the individual members." *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

In their brief, the Organizations fail to establish that their individual members would have standing to sue. As discussed above, an individual has Article III standing to seek injunctive relief only if he can demonstrate that he "is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). Under this test, the Organizations must demonstrate at least one of their members (a) is under threat of suffering a concrete and particularized injury, (b) the injury is traceable to Inhance's purported TSCA violations or alleged delay in submitting a SNUN, and (c) the injury is redressable by granting the Organizations' requested injunction. This they cannot do.

"To establish associational standing, the plaintiff association must 'make specific allegations establishing that at least one *identified* member had suffered or would suffer harm.'"

Comité de Apoyo a los Trabajadores Agrícolas v. Perez, 148 F. Supp. 3d 361, 371 (D.N.J. 2015) (quoting Summers, 555 U.S. at 497–498)). In support of their contention that they have satisfied associational standing requirements, the Organizations submitted declarations from four individual "members" of their organizations. But like Mr. De La Rosa, these declarants fail to establish anything more than generalized concerns about the potential harms from PFAS that may be present in some plastic containers. Notably, not one of these declarants has suffered any adverse health effect caused by PFAS exposure from fluorinated containers; nor have any of these declarants alleged that any of the plastic containers they used were actually fluorinated by Inhance, let alone identified the products as issue so that they could be traced back to Inhance. And also like Mr. De

La Rosa, these critical shortcomings doom their claims of standing. A closer look at the declarations makes this plain.

- Jose Bravo: Jose Bravo is a "Member of the Board of Directors" of CEH. Bravo Decl. ¶ 1. Mr. Bravo's declaration states that "[a]s a child," he "was constantly exposed to plastic pesticide drums, and we then in turn used some of those plastic pesticide drums to store water for use around the house." Id. at ¶ 8. He further states that he is "currently in good health" but is "concerned that PFAS exposure can harm [his] health." Id. at ¶ 9 (emphasis added).
- *Kaya Sugerman*: Kaya Sugerman is the Director of Illegal Toxic Threats for CEH. Sugerman Decl. ¶ 1. In her declaration, Ms. Sugerman states that she "ha[s] had continuous contact with plastic containers that *may be* fluorinated whether cleaning products, engine oil I add to my vehicles, art supplies for the oil and acrylic painting I have done for 20+ years, haircare bottles, and more." *Id.* at ¶ 4 (emphasis added). Ms. Sugerman further states that she is "deeply concerned about both [her] individual exposure, and the collective exposures to LCPFASs in communities and the environment." *Id.*
- *Timothy Whitehouse*: Timothy Whitehouse is the Executive Director and a Board Member of PEER. Whitehouse Decl. ¶ 1. Mr. Whitehouse's declaration states that he has "had numerous contacts with plastic containers that *may be* fluorinated and their contents, as well as materials that were previously stored or transported in such containers. These include containers for cleaning products, home improvement products, automotive supplies, fuels, and food." *Id.* at ¶ 10 (emphasis added). Mr. Whitehouse states that he is "deeply concerned about [his] exposure to LCPFACs" and "feel[s] anxious" about his "exposure and exposures to [his] family." *Id.* at ¶ 11.

• *Kyla Bennett*: Kyla Bennett is the Northeast and Mid-Atlantic Director and Director of Social Policy for PEER. Bennett Decl. ¶ 1. In her declaration, Ms. Bennett explains that her "shampoo and conditioner that [she] used for years came in plastic containers" and that when she "used these personal care products, [she] came into contact with the containers and their contents." *Id.* at ¶ 12. Ms. Bennett further states that she has "had numerous contacts with plastic containers that *may be* fluorinated, together with their contents, as well as materials that were previously stored or transported in such containers." *Id.* at 11 (emphasis added). In her declaration, Ms. Bennett discusses her Spring 2020 diagnosis of a hemangioblastoma. *Id.* at ¶ 13. Ms. Bennett states that she is "anxious that [she is] more susceptible to environmental contaminants." *Id.* at ¶ 14.

The risk ("concern") of possible ("may be") exposure to PFAS and LCPFACs is insufficient to establish a concrete and particularized injury. *See Natural Res. Def. Council v. EPA*, 464 F.3d 1, 6 (D.C. Cir. 2006) ("Were all purely speculative 'increased risks' deemed injurious, the entire requirement of actual or imminent injury would be rendered moot, because all hypothesized, nonimminent 'injuries' could be dressed up as 'increased risk of future injury.' ") (citation omitted). Rather, the Organizations must establish that one of their individual members faces an "actual or imminent" threat of injury. *See Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 278 (3d Cir. 2014) ("[P]laintiffs relying on claims of imminent harm must demonstrate that they face a realistic danger of sustaining a direct injury from the conduct of which they complain."); *Public Int. Rsch. Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 122 (3d Cir. 1997) ("When a plaintiff claims that a defendant's threatened injury is the source of his standing, he must show that the threatened injury is so imminent as to be certainly impending.'").

But these declarants claim nothing more than that they will continue to use plastics that may be fluorinated, which may increase their risk of exposure. This is insufficient. The Article III injury's imminence requirement is "stretched beyond the breaking point when, as here, the plaintiff alleges only an injury at some indefinite future time, and the acts necessary to make the injury happen are at least partly within the plaintiff's own control." Lujan, 504 U.S. at 564 n.2. See also Pennsylvania Prison Soc. v. Cortes, 508 F.3d 156, 166 (3d Cir. 2007) ("[A]llegations of injury at some indefinite future time—where the acts necessary to make the injury happen are within the . . . plaintiffs' own control—lack the high degree of immediacy required to constitute injury in fact and provide Article III standing."). Precisely so here: These "someday" possibilities of exposure, where that exposure would be caused by the declarants' own actions, fail Article III's injury requirement. And while the declarants state that they are "concerned" about their families' exposure to LCPFACs or PFAS because they are "aware that exposure to PFAS . . . can cause adverse health effects," such general knowledge, without more, is similarly insufficient to evince an imminent threat of harm. See Public Int. Rsch. Grp., 123 F.3d at 120 (Plaintiff's "knowledge that [defendant] exceeded the effluent limits set by its NPDES permit does not, by itself, demonstrate injury or threat of injury."). Further, these declarants have not distinguished themselves in any way from the general population; generalized grievances shared by the public at large do not provide individual plaintiffs with standing. See, e.g., Valley Forge Christian Coll. v. Americans United for Separation of Church & State, 454 U.S. 464, 475 (1982); Warth v. Seldin, 422 U.S. 490, 500 (1975).

Even assuming the general "concern" and "anxiety" the Organizations' declarants experience constitute a particularized injury, they still fail to demonstrate that their alleged injuries are causally connected to Inhance's challenged conduct. *See Duke Power Co. v. Carolina Env't*

Study Grp., Inc., 438 U.S. 59, 72 (1978) (Article III standing requires "not only a 'distinct and palpable injury,' to the plaintiff . . . but also a 'fairly traceable' causal connection between the claimed injury and the challenged conduct.") (citations and internal quotation marks omitted).

The timing of Inhance's SNUN submission is a purely procedural question; it has no bearing on whether or not these declarants face a risk of PFAS exposure from plastic containers. Whether or not to ban fluorination of containers industry-wide is one for Congress or EPA, not for Intervenors to solve through this lawsuit. 15 U.S.C. § 2616. The Organizations' claim that their members "have been personally impacted by the failure of Inhance to comply" with the Rule, Intervenors' SJ Mem. 10, is entirely unsupported by the cited declarations of Mr. Bravo and Ms. Sugerman. There is no mention in Mr. Bravo's or Ms. Sugerman's declarations about how Inhance's alleged violation of TSCA's SNUR—again, an alleged failure to file a notice on time has "personally impacted" them whatsoever. See Pennsylvania Prot. & Advoc., Inc. v. Houston, 136 F. Supp. 2d 353, 360–361 (E.D. Pa. 2001) ("at the summary judgment stage, the plaintiff can no longer rest on mere allegations, and must set forth evidence to support" the elements of Article III standing). Indeed, none of the declarants contend that their "concerns" stem from Inhance's alleged delay in submitting a TSCA SNUN or any alleged violation of TSCA by Inhance. See Summers, 555 U.S. at 499 (speculation that "it is certainly possible—perhaps even likely—that one individual will meet [the standing] criteria . . . does not suffice.").

In fact, the only arguably specific injury alleged—Ms. Bennett's hemangioblastoma—was diagnosed in 2020, two years before the date the Organizations argue Inhance should have submitted a SNUN. *See* Bennett Decl. ¶ 13; Intervenors' SJ Mem. 22 (contending that "Inhance knew or should have known that its customers and other container recipients were 'processing' LCPFACs and thereby 'engaging in a significant new use' no later than March 1, 2022"). There

can be no causal connection between an alleged injury and the complained-of conduct when the alleged injury predates the Inhance's alleged conduct by years. And while Ms. Bennett ties her alleged exposure to PFAS to plastic shampoo bottles, she does not allege that Inhance fluorinated the bottles at issue, let alone provide basic information about the shampoo bottles at issue. Bennett Decl. ¶ 12.

Because none of the alleged injuries suffered by the Organizations' members is fairly traceable to Inhance's conduct, the Organizations cannot establish standing. *See Rogers v. A.O. Smith Corp.*, 602 F. Supp. 3d 748, 761 (E.D. Pa. 2022) (granting summary judgment for defendant General Electric where "[p]laintiff has failed to produce sufficient evidence for a jury to conclude that he was exposed to a[] potentially asbestos-containing [product] manufactured by General Electric at all, let alone to such an extent that the exposure was a substantial factor in causing his injury").

Setting these glaring issues aside, the Organizations have also failed to establish that any of their members satisfy the redressability requirement. Assuming the relief requested (enjoining Inhance from providing fluorination services until the SNUN is resolved) is granted, the Organizations' members' purported injuries will not be remedied. The amount of time that the injunction would be in place is likely to be very short in duration, and other companies will likely continue fluorinating containers in the meantime. *See* Iyer Decl. ¶7. The Organizations' members will still not know whether any particular container (i) was fluorinated by a third party, (ii) was fluorinated by Inhance before the injunction took effect; (iii) not fluorinated but nonetheless contains PFAS or LCPFACs due to materials used in manufacturing the container itself; or (iv) contains PFAS or LCPFACs introduced by the product stored within the container. Thus, even if the Court enjoined Inhance from providing fluorination services entirely, the Organizations'

declarants would still feel "concern" about their exposure because they, admittedly, do not know whether any particular plastic container they came into contact with was fluorinated by Inhance. *See* Bravo Decl. ¶ 9; Sugerman Decl. ¶ 4; Whitehouse Decl. ¶ 11; Bennett Decl. ¶ 16.

The general statements contained in the declarations are insufficient to establish a "substantial likelihood" that Inhance's alleged violations of TSCA caused the kinds of injuries alleged. Nor is there anything in the declarations suggesting that the declarants' general "concerns" about PFAS and LCPFACs could be redressed by enjoining Inhance's fluorination technology until the EPA completes the SNUN process. Accordingly, the Organizations are mere "concerned bystanders" with no standing to maintain this action. *See Public Int. Rsch. Grp.*, 123 F.3d at 121 ("[A]bsent a showing of actual, tangible injury to the River or its immediate surroundings, PIRG's members are no less 'concerned bystanders' than any other citizen who takes an interest in our environment.").

Because the Organizations have not established that any of their individual members would have standing to sue, the Organizations cannot establish associational standing. *See American Chiropractic Ass'n v. American Specialty Health Inc.*, 625 F. App'x 169, 172 (3d Cir. 2015) (affirming dismissal of association's claims for lack of associational standing because the association "failed to show that any of its members had standing in their own right").

2. The Organizations fail to establish organizational standing.

The Organizations have not tried to assert standing on organizational grounds. Even if they had, such arguments would, too, fail, because they have not presented any evidence that they as organizations have suffered a concrete injury. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (To bring suit as an organization, a plaintiff must establish a "concrete and demonstrable injury to the organization's activities—with [a] consequent drain on the

organization's resources—[that] constitutes far more than simply a setback to the organization's abstract social interests."). And it would be extremely difficult for them to do so: Where "organizations are squarely focused on warning the public about health hazards in consumer products," then their efforts to do just that cannot be the basis for an organizational injury. *E.g.*, *Environmental Working Grp. v. FDA*, 301 F. Supp. 3d 165, 171 (D.D.C. 2018). In the same vein, organizations are not injured where they have done nothing that stretches "beyond their typical expenditures" of resources. *Id.* at 172. Given PEER and CEH's longtime focus on PFAS-related activism, they cannot claim harm sufficient to confer constitutional standing from engaging in their "typical" activities. Intervenors' SJ Mem. 9–10 (noting that their "organizational purposes are directly served" by this lawsuit).

II. SUMMARY JUDGMENT IS PREMATURE

Intervenors' summary-judgment motion is just as precipitous as the Government's, and each of the procedural-prematurity arguments Inhance advances in its opposition to the Government's motion apply with equal force here: This lawsuit is not ripe. Discovery has not yet commenced. Material facts remain in dispute. Intervenors have cited no reason that this case should be resolved without allowing Inhance the opportunity to test the factual assertions made in their summary judgment papers. *See* Inhance Opp. to Gov't SJ Br. 7–12.

III. INHANCE DID NOT VIOLATE TSCA

A. The Statute Does Not Restrict Inhance's Use.

The substance of Intervenors' motion is similarly unmerited, though for different reasons. Intervenor' claims are premised on their assertion that a party subject to TSCA's significant new use provisions must "submit a notice to EPA of its intent to manufacture or process the substance for the significant new use at least 90 days before these activities will be *initiated*" and that the

new use "cannot *begin*" until after EPA has conducted its risk determination. Intervenors' SJ Mem. 12 (emphases added). This statutory scheme, when it applies, is straightforward: The party must submit the required notices, and may embark upon its proposed new use only when EPA gives its go-ahead. But the question here is whether this "guiding premise of the TSCA SNUR provisions" applies to Inhance, a party that—as the Intervenors acknowledge—has been engaged in an "ongoing" use that predates the SNUR's proposal and promulgation. Intervenors' SJ Mem. 11.

Intervenors build a feeble bridge to statutory liability. In their view, Inhance's existing use ceased to be ongoing when EPA proposed the SNUR. By this logic, to preserve its fluorination process as an existing use, Inhance should have sought an exemption decreeing that its decades-old use had not, in fact, suddenly become a new one. That view is not grounded in the statutory text, which applies only to a "significant new use." The statute outlines factors relating to a use that is contemplated but not yet initiated. 15 U.S.C. § 2604(a)(2) (looking to "projected volume," "the extent to which a use *changes*" exposure levels, and "reasonably *anticipated* manner and methods") (emphases added). ¹

And even if "new" could mean "old" under TSCA, there is nothing in the summary-judgment record indicating EPA ever suggested that Inhance would have needed to seek a regulatory exemption to avoid the SNUR's reach. Inhance, and the industry to which it belongs, is not covered by the plain terms of the SNUR. *See* Inhance Opp. to Gov't SJ Br. 12–16. Instead,

¹ Because earlier-enacted statutes only permitted regulators to "impose restrictions after manufacture begins," Congress crafted TSCA in this way to avoid the sort of disruptive, post-hoc action that Plaintiffs ask the Court to order. S. Rep. No. 57-010, at 5 (1976), as reprinted in 1976 U.S.C.C.A.N. 4491, 4495. According to a 1976 Senate Commerce Committee report, TSCA differs from "these other statutes" by authorizing regulation before manufacturing ever begins—which is when "the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest. Frequently, it is far more painful to take regulatory action after all of these costs have been incurred." *Id*.

the evidence shows that when EPA adopted the Final Rule, the agency believed it was promulgating a Final Rule with a substantially narrower scope than the sweeping one Plaintiffs now espouse. EPA tailored the rule to reach a specific subset of the regulated community, which is why the agency's own analysis of the SNUR "assumes that few, if any, entities are expected to submit a SNUN." Ex. 40 (EPA Economic Analysis of SNUR (June 18, 2020)).

There are other reasons that the SNUR does not apply to Inhance. Any LCPFACs generated as a result of Inhance's fluorination technology are outside the reach of the SNUR. See Inhance Opp. to Gov't SJ Br. 14–16. That is because any LCPFACs are unintentionally present within the partially fluorinated exposed surfaces of plastic articles. See 40 C.F.R. § 720.3(m). As a result, they are impurities and are exempt from TSCA's significant new use provisions. See 40 C.F.R. § 721.45(d). Intervenors ignore this to argue instead that any LCPFACs found in containers fluorinated by Inhance *must* be subject to the SNUR. They get there by stating that whether those LCPFACs are produced "unintentionally do[es] not exempt them from the SNUR." Intervenors' SJ Mem. 20. That assertion is plainly contradicted by EPA's governing regulations, which define an "impurity" as a "chemical substance which is unintentionally present with another chemical substance," 40 C.F.R. § 720.3(m) (emphasis added), and then go on to explicitly exempt impurities from the SNUR notification requirements, 40 C.F.R. § 721.45(d). Intervenors' references to EPA's non-binding open letter to industry, Intervenors' SJ Mem. 20–21, do not displace the clear text of the agency's own regulations. See Christopher v. SmithKline Beecham Corp., 567 U.S. 142, 155 (2012) (no deference to agency statement where "plainly erroneous or inconsistent with the regulation").

The Government also has failed to provide fair notice to Inhance of its intention to apply the SNUR to Inhance's fluorination processes. In the rulemaking itself, EPA said nothing about fluorination of containers. *See Significant New Use Rule*, 85 Fed. Reg. 45109 (July 27, 2020). The agency did not provide any guidance on the issue until it issued a notice of violation to the company years later, in March 2022, *see* Ex. 18 (Notice of Violation Letter). EPA issued an open letter to the industry two weeks later, asserting for the first time that the rule applied to the fluorination industry. Iyer Decl. ¶ 38; Ex. 19. Inhance moved quickly to obtain the necessary information to prepare its SNUNs and submitted the relevant notice shortly thereafter. Iyer Decl. ¶ 39–40; Exs. 3, 4.

Finally, TSCA does not contain a notification requirement for a fluorinator like Inhance. Intervenors stand alone in seeking relief based on this theory: For its part, the Government does not allege a statutory violation based on Inhance's alleged failure to superintend each of its customers' compliance with the SNUR. *See generally* Gov't SJ Mem. And for good reason. Intervenors argue that Inhance should have begun this customer-notification process by March 2022, when it received an NOV from EPA. Intervenors' SJ Mem. 22. But the NOV did not demand that Inhance take this action. *See* Ex. 18 (Notice of Violation). And this argument ignores that TSCA imposes no obligation on Inhance to help EPA apply a legally inapplicable SNUR to Inhance's own customers—especially before EPA has taken final agency action.

For all of these reasons, Inhance was not legally obligated to submit a SNUN. It did so under threat of an enforcement action, and only under protest. Exs. 3, 4. But that does not mean that it was also required to voluntarily stop fluorinating while EPA reviewed the SNUN, as suggested in Intervenors' brief. *See* Intervenors' SJ Mem. 21.

Even if Intervenors are right that Inhance was under a duty to file a SNUN, they fail to establish any ongoing, remediable violation of TSCA resulting from the period preceding Inhance's SNUN submission. Injunctive or declaratory relief is unavailable for alleged violations

of the statute that relate to past conduct—like Inhance's alleged unlawful failure to timely submit SNUNs. See Corliss v. O'Brien, 200 F. App'x 80, 84 (3d Cir. 2006) (per curiam) ("Declaratory judgment is inappropriate solely to adjudicate past conduct" and is also not "meant simply to proclaim that one party is liable to another."); Blanciak v. Allegheny Ludlum Corp., 77 F.3d 690, 698 (3d Cir. 1996) (injunctive relief unavailable to remedy a claim's "specific allegations" that "target past conduct"). Nothing in the summary-judgment record establishes Intervenors' right to relief under TSCA for Inhance's later submission of the SNUNs—even if the notices were required.

For these reasons, as well as those Inhance has stated in its opposition to the Government's motion for summary judgment, Intervenors cannot prevail on summary judgment.

B. The Factual Record Does Not Warrant Summary Judgment In Intervenors' Favor.

Until this point in their briefs, the Government and Intervenors make largely the same arguments. But then they part ways. Where the Government relies on a small handful of materials plucked from EPA's administrative review, the Intervenors introduce a flurry of new documents in an effort to compensate for the absence of an actual summary-judgment record. None of these materials establishes the absence of a genuine dispute of material fact that would entitle Intervenor-Plaintiffs to summary judgment.

If anything, the Intervenors' newly introduced "evidence" shows why this case is ill-suited for summary resolution at this stage. Intervenors' studies lack supporting data, are riven with methodological error, and are devoid of reasoned analysis. Their declarations document general grievances with PFAS broadly in context unrelated to the matter before the Court but do not constitute competent summary-judgment evidence that would prove Inhance's fluorination technology amounts to a statutory violation. And their comment letters to EPA—submitted here,

despite the pendency of EPA's consideration—are filled with discussion of immaterial issues and speculative assertions. Summary judgment cannot be awarded on this record.

1. Expert opinion dressed up as "fact."

Intervenors' summary-judgment motion can succeed only if the Court accepts materials that have not been tested through discovery and are of uncertain evidentiary quality. Start with the studies "summarized" in the Leiva declaration. Leiva Decl. ¶ 3. The Court is given no indication of the studies' underlying data, sample size, or methodology. And what little information is available about these studies does not suggest they have much usefulness in resolving this case against Inhance.

Intervenors' brief also is peppered with references to studies and data that have nothing to do with Inhance's business practices. Among other things, Inhance does not fluorinate containers that hold "olive oil, mayonnaise, and ketchup," which renders Intervenors' extensive discussion of the amounts of PFAS in the same at best irrelevant and at worst, misleading. Intervenors' SJ Mem. 15–16, Iyer Decl. ¶19.

And, as those very studies would appear to show, the identity of a container's contents can "significantly" change the measured concentration of PFAS, regardless of the composition of the container itself. *See* Leiva Decl. ¶ 6. Inhance does not fill the containers, nor does it manufacture any of the containers' contents. Whether and to what extent those contents affect PFAS concentration is therefore outside of Inhance's control, and is irrelevant to this litigation.

Worse still, most of the studies post-date the effective date of the SNUR, so it would have been impossible for EPA to have considered them when it proposed and issued the SNUR. Only one study appears to have evaluated fluorinated containers that had been treated by a predecessor to Inhance. *See* Inhance Response to SOMF ¶ 4. And Intervenors offer nothing other than

conjecture to conclude that this one study related to Inhance's predecessor-in-interest was even known to Inhance. *See* Intervenors' SJ Mem. 19 n.6.

Because Plaintiffs have filed a motion for summary judgment at the pleading stage, none of these purported "facts"—which are really just glorified expert opinion—has been put through the crucible of discovery. Granting a Rule 56 motion now would end the litigation without ever giving Inhance the opportunity to develop its substantive defense to liability. *See In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 739 (3d Cir. 1994) ("[I]t is important that each side have an opportunity to depose the other side's experts in order to develop strong critiques and defenses of their expert's methodologies"). And granting relief would also transgress the procedural rights guaranteed to defendants. *See id.*

When a party moves for summary judgment by relying on expert opinion that has not been subjected to discovery, this Court routinely declines to award relief under Rule 56. See, e.g., Lanning v. Southeastern Pa. Transp. Auth., 176 F.R.D. 132, 145 (E.D. Pa. 1997) (denying motion for summary judgment "as premature" where "expert discovery ha[d] not even started"); United States v. Sunoco, Inc., 644 F. Supp. 2d 566, 582 (E.D. Pa. 2009) (same); Coates v. Metropolitan Prop. & Cas. Ins. Co., No. CV 19-5143, 2020 WL 6220744, at *1 n.2 (E.D. Pa. June 11, 2020) (same). That course is appropriate here. If the case proceeds beyond the pleading stage, the Court deserves the benefit of a full factual record before deciding whether the issues may be resolved without a trial on the merits. Hines v. Consolidated Rail Corp., 926 F.2d 262, 272 (3d Cir 1991) ("A detailed factual record is required at the evidentiary stage, particularly when a summary judgment may result."). And Inhance deserves the opportunity to test Plaintiffs' proffered opinions, put forward its own experts to rebut them, and file its own summary-judgment motion

on a fully developed record. *See Paoli*, 35 F.3d at 739 ("[F]airness suggests that each side should have an equal opportunity to depose the other side's experts.").

2. Faulty causal connections.

Intervenors offer several declarations that purport to establish Inhance's liability under TSCA, and yet the declarations stop short of establishing any link between Inhance and the containers they have encountered. Take the Bravo declaration. The document discusses the risks of PFAS generally and the declarant's potential exposure by performing "regular household chores (i.e., floor products, air sprays, or cleaning products), and working [his] yard or garage." Intervenors' SJ Ex. 1, A-7. Yet nowhere does the declaration link any of these purported harms to a fluorinated container that contains LCPFAC chemical substances—nor a container that was fluorinated by Inhance. The Bravo declaration therefore does nothing to help Intervenor-Plaintiffs bear their Rule 56 burden.

The other declarations are similarly misdirected but veer even further off course. Nothing in the Sugerman, Whitehouse, or Bennett declarations connects any of those declarants' plastic-container experiences to Inhance. Each declaration contains an identical statement decrying that there are "no labels identifying whether particular containers are fluorinated and what LCPFACs they contain." Sugerman Decl. ¶ 5; Whitehouse Decl. ¶ 11; Bennett Decl. ¶ 16. But there is no such requirement, and these statements reveal that it is at best speculative that any declarant has encountered, much less been harmed by, a PFAS-containing article that Inhance fluorinated.

The declarations are therefore immaterial to the issues implicated by this lawsuit. It is likewise immaterial that these unidentified plastic containers lack labels indicating whether they have been fluorinated. Such labels are not required under TSCA or any of its implementing

regulations, so their absence does not show a statutory violation even if Inhance fluorinated the containers. *See generally* 15 U.S.C. §§ 2601–2629.

All told, Intervenors' declarations offer policy suggestions that are better directed to Congress, which drafted the statute, or to EPA, which is charged with promulgating rules under TSCA. Perhaps unsurprisingly, they echo comments Intervenor-Plaintiffs recently submitted to the agency. And Intervenors have placed these same comments in the summary-judgment record—even though the comments cite all of the same studies the Leiva declaration asks this Court to assess anew. Leiva Decl. ¶¶ 6–21;Intervenors' SJ Ex. 18, A-573–624.

3. Inadmissible evidence.

Many other professed statements of "fact" contained in Intervenors' summary-judgment papers are similarly not competent summary-judgment evidence. Intervenor-Plaintiffs liberally cite their own recent comment letters to EPA, for example, while failing to provide any other corroboration for their assertions. This is insufficient under Rule 56. *See Freedom Card, Inc. v. JPMorgan Chase & Co.*, 432 F.3d 463, 478 (3d Cir. 2005) (discounting, on summary judgment, a party's "uncorroborated and self serving proclamations").

When Intervenors do rely on facts drawn from an external source, the facts they put forward are largely immaterial. For example, Intervenors seize on a separate Inhance process that converts perfluorooctanoic acid (PFOA) in fluoropolymers (i.e., not article-containers) to non-LCPFAC by exposing the fluoropolymers to fluorine. *See* Intervenors' SJ Mem. 19–20 n.6. That process is not at issue in this litigation. The cited patent application, therefore, does not prove any of Intervenors' allegations, including their claim that Inhance had fair notice of the SNUR's applicability.

Intervenors rely on materials that are ordinarily subjected to discovery and evaluated for their admissibility before a court considers them on summary judgment. The same should hold true here. *See Jones v. Judge Tech. Servs. Inc.*, No. CIV.A. 11-6910, 2013 WL 5777159, at *3 (E.D. Pa. Oct. 25, 2013) ("only evidence which is admissible at trial may be considered in ruling on a summary judgment motion"). To take just one example, Intervenors make their case by introducing certain communications between EPA and state administrative agencies. Intervenors' SJ Ex. 50, A-1210. These and similar communications have not previously been made available to Inhance, and Intervenors' reliance on them here raises significant procedural and evidentiary issues.

Inhance is entitled to discovery about this precise category of communications. *See* Kushner Decl. ¶ 10. And the admissibility of these communications, which present chain-of-custody questions, among other evidentiary problems, is far from certain. Intervenors' introduction of this EPA correspondence in its summary-judgment motion—even though the Government could have, but notably did not—suggests that the Court should doubt the Plaintiffs' assurances that a pre-discovery summary judgment disposition of this case would be proper. *See Costlow v. United States*, 552 F.2d 560, 564 (3d Cir. 1977) ("[W]here the facts are in the possession of the moving party, a continuance of a motion for summary judgment for purposes of discovery should be granted almost as a matter of course.").

IV. THIS COURT SHOULD DENY INJUNCTIVE RELIEF

A. This Court May Exercise Its Equitable Discretion To Deny Injunctive Relief.

Intervenors argue that if the Court finds Inhance liable for violations of TSCA, it has no choice but to issue an injunction. That is wrong. Neither the Supreme Court nor Congress *mandates* the injunctive relief Intervenors seek.

It is strongly disfavored to strip a court of its discretion to do equity—and to do so requires far more than the misleading justifications Intervenors have produced here. As the Supreme Court stated in *Weinberger v. Romero-Barcelo*, "a major departure from the long tradition of equity practice should not be lightly implied." 456 U.S. 305, 320 (1982). The Third Circuit has echoed this cautionary warning, noting the "high standard" required to overcome the presumption in favor of a court's equitable discretion. *Chester ex rel. Nat'l Lab. Rels. Bd. v. Grane Healthcare Co.*, 666 F.3d 87, 95 (3d Cir. 2011). *See also Natural Res. Def. Council v. Texaco Refin. & Mktg., Inc.*, 906 F.2d 934, 937 (3d Cir. 1990) (holding that district court abused its discretion by "presuming irreparable harm and not explicitly applying the traditional equitable standard in determining whether an injunction was appropriate").

Contrary to what Intervenors imply (at 24–25), "the Supreme Court has explicitly rejected" a mandate or presumption to impose injunctive relief "[i]n the area of environmental statutes." United States v. Massachusetts Water Res. Auth., 256 F.3d 36, 48 (1st Cir. 2001); accord Town of Huntington v. Marsh, 884 F.2d 648, 651 (2d Cir. 1989) (same). Later Supreme Court precedent reaffirms, rather than weakens, this pronouncement. For instance, in Oakland Cannabis Buyers, the Supreme Court reiterated that the presumption in favor of equitable discretion is a very strong one, and can only be overcome where equitable relief is "textually required by any 'clear and valid legislative command." United States v. Oakland Cannabis Buyers' Coop., 532 U.S. 483, 496 (2001). See also Massachusetts Water Res. Auth., 256 F.3d at 56 (citing Oakland Cannabis Buyers to defend district court's equitable discretion). Here, there is no such command.

TSCA contains no textual requirement that a court grant prohibitory injunctive relief. For that reason, TSCA is starkly distinct from the Endangered Species Act (ESA), the statute Intervenors argue controls the outcome on this issue. Intervenors' SJ Mem. 27. The ESA stands

alone, or nearly so: Per the Supreme Court, "[o]ne would be hard pressed to find a statutory provision whose terms were any plainer than those in Section 7 of the [ESA]." *Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 173 (1978). The Supreme Court directly contrasted the ESA to other statutory language that "qualified the obligation of federal agencies" via more permissive and flexible terminology. *Id.* at 181. And unlike the majority of other environmental statutes, "[the ESA's] language admits of no exception" outside the grant of injunctive relief. *Id.* at 173. "The pointed omission of th[at] type of qualifying language . . . revealed a conscious decision by Congress" to prescribe one remedy alone—prohibitory injunctive relief. *Id.* at 185. But in *Tennessee Valley*, the Supreme Court made clear that the ESA is the exception, not the rule. And Intervenors' notable failure to ground their analogy to the ESA in any of TSCA's actual text is proof enough that *Tennessee Valley* does not control here. Indeed, as the Seventh Circuit recently held, "[a]bove all, the issuance of injunctive relief [under TSCA] remains discretionary." *Liebhart v. SPX Corp.*, 998 F.3d 772, 780 (7th Cir. 2021) (affirming district court's denial of injunctive relief under TSCA).

That holding is borne out by a closer look at TSCA's statutory language. TSCA is highly similar to the environmental statutes that the Supreme Court and other courts have held *do* provide for equitable discretion. For instance, TSCA provides for other, non-injunctive remedies such as civil and criminal penalties. 15 U.S.C. § 2615(a)–(b). The same was true—and dispositive—in *Romero-Barcelo*, a case involving the Federal Water Pollution Control Act (FWPCA). There, the Supreme Court concluded that because the statute itself "provide[d] for fines and criminal penalties," "[a]n injunction is not the only means of ensuring compliance." *Weinberger*, 456 U.S. at 314. As a result of the statute's remedial flexibility, the Supreme Court rejected the First Circuit's imposition of an "absolute statutory obligation to stop any discharges of pollutants" even

though the defendant had violated the FWPCA. *Id.* at 311. Similarly, other courts of appeal have reasoned that EPA's power to "issue administrative orders for minor [Safe Drinking Water Act] violations, and to collect fines for those violations" was "evidence for the preservation of equitable discretion." *Massachusetts Water Res. Auth.*, 256 F.3d at 52. *See also Environmental Conservation Org. v. City of Dallas*, 529 F.3d 519, 530 (5th Cir. 2008) ("[T]he district court was not bound to order the immediate cessation of all violations [of the Clean Water Act]. Traditional equitable principles control the decision to enter an injunction. . . . The district court might even have denied injunctive relief altogether.").

Intervenors attempt to avoid this fatal flaw in their argument by a selective reading of TSCA. First, they claim that the existence of civil and criminal penalty provisions are immaterial because they do not appear in the citizen suit provision. Intervenors' SJ Mem. 27 n.8. That is irrelevant: They appear in the statute, and "it is necessary to 'look to the statute's remedial framework as a whole" in determining whether equitable discretion exists. *Massachusetts Water Res. Auth.*, 256 F.3d at 48 (internal quotation marks and alterations omitted). Next, Intervenors claim that the enforcement provision of Section 17 must be read to provide for only one type of injunctive relief. Intervenors' SJ Mem. 28 n.9. That is facially inaccurate: That provision explicitly provides for remedies outside of restraining the challenged conduct. 15 U.S.C. § 2616(a)(1)(A)–(D). Intervenors' assertion that this provision is necessarily tethered to an award of injunctive relief is belied by the plain text of the statute, which links these remedies via "or"—not "and." *Id.* They are not free to "replace the actual text [of the statute] with speculation as to Congress' intent." *Magwood v. Patterson*, 561 U.S. 320, 334 (2010).

Intervenors have also provided no basis for this Court to abandon the traditional four-factor test for injunctive relief because of Inhance's purported knowledge about its purported violations.

To start, knowledge is a factual question, and in place of undisputed facts, Intervenors substitute unfounded speculation based on their own misapprehension of the timeline of events, *see supra* at 5–6; Iyer Decl. ¶ 36. In any event, Intervenors get the law wrong. In their haste to urge this Court to skip the equities, they ignore an important portion of the cited opinion that immediately follows their preferred rule: "[T]he law of injunctions differs with respect to *governmental plaintiffs* (or private attorneys general) as opposed to private individuals." *United States v. Bethlehem Steel Corp.*, 38 F.3d 862, 868 (7th Cir. 1994) (quoting *EPA v. Environmental Waste Control, Inc.*, 917 F.2d 327, 332 (7th Cir. 1990)) (emphasis added). Intervenors are *not* governmental plaintiffs, and thus they may not invoke this exception to the four-factor test. And the facts of *Bethlehem Steel* also differ significantly from the facts here: In that case, defendants knew they were producing admittedly hazardous waste, sought and received a permit from EPA, and then failed to comply with any of the permit's conditions. *Id.* at 864–865. The Seventh Circuit held that, in light of the defendant's knowledge of its *own permit* requirements, the district court need not have weighed the equities before ordering the defendant to comply with the permit's terms. *Id.* at 867.

For all of these reasons, Intervenors' attempts to strip this Court of its equitable authority should fail.

B. The Equities Do Not Weigh In Favor Of Granting An Injunction.

While Intervenors purport to ask for an injunction on the merits, their motion—filed this early in the lawsuit, before discovery—essentially requests a preliminary injunction merged with a decision on the merits. "A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 24 (2008).

In any event, to prevail on any claim for injunctive relief, the moving party must demonstrate a likelihood, as opposed to a mere possibility, that they will succeed on the merits; that they personally are "likely to suffer irreparable harm in the absence of preliminary relief"; that "the balance of equities tips in [their] favor"; and that an "injunction is in the public interest." *Id.* at 20.² The Third Circuit requires that "the party seeking the injunction meet[] the threshold on the first two" factors. *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 (3d Cir. 2017). If the party fails to demonstrate either likelihood of success or irreparable harm, then the inquiry should end. *Id.* Because Intervenors here have failed on both counts, this Court should deny their request for injunctive relief.

Intervenors have not demonstrated they are likely to succeed on the merits. As discussed *supra*, it is clear from the plain text of the Rule and from the limited evidence before the Court that Inhance's *old* use is not subject to a Significant *New* Use Rule. Furthermore, even if Inhance were subject to the Rule, its manufacturing process results in the production of PFAS as impurities, as opposed to byproducts, also discussed *supra*. Finally, Intervenors' claims about Inhance's purportedly noncompliant actions are overblown and inaccurate. In fact, the evidence demonstrates that Inhance *has* complied with EPA's requests for information, including by submitting SNUNs despite the company's good-faith belief that it was not subject to the SNUR. Iyer Decl. ¶ 39. Inhance maintains that this evidence shows that its process does not result in the production of any chemical substance intended to be regulated by TSCA, and that the final determination on this critical factual issue rests with the EPA administrative process, not with Intervenor-Plaintiffs' independent, unverified research. It is far from clear how these facts—which strike at the heart of whether Inhance is even subject to the SNUR, let alone in violation of it—can support a finding that Intervenors are likely to succeed on the merits of their TSCA claim.

² The standard for granting permanent injunctive relief involves an analysis of very similar factors, including whether plaintiffs have suffered an "irreparable injury," whether "the balance of hardships" weighs in favor of equitable relief, and whether "the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

Even if Intervenors had made the requisite showing of likelihood of success, their claim for injunctive relief still fails under the second factor of the Winter test. See America Unites for Kids v. Lyon, No. CV 15-2124, 2015 WL 2352184, at *6 (C.D. Cal. May 18, 2015) (denying preliminary injunctive relief to plaintiffs including Intervenor PEER because of a lack of irreparable harm). Intervenors have not demonstrated that they would be harmed at all—let alone irreparably harmed—absent an injunction. Intervenors provide no facts about their own exposure to containers known to have been fluorinated by Inhance, nor do they provide any facts about any documented health consequences from those containers—to themselves or to others. Rather, Intervenors engage in sweeping generalizations based on a long recitation of facts from several independent, and unverified, studies. Intervenors' SJ Mem. 36-50. Aspects of their supposed arguments are wholly irrelevant to the rule at issue, such as the possible health effects of exposure to short-chain PFAS—which are not the subject of the long-chain PFAS Rule. Id. at 36, 40. Yet other studies they provide are irrelevant to whether *Inhance's* fluorination technology is the cause of PFAS exposure, such as what may or may not occur to plastic containers in recycling plants long after those containers have left Inhance's control. *Id.* at 44, 49.

Nowhere in all of those pages of briefing is there evidence that these particular Intervenors—who must demonstrate irreparable harm to themselves in order to satisfy the traditional four-factor test for injunctive relief—are likely to be injured by any of Inhance's challenged conduct. In fact, the opposite is true: Based on Intervenors' own argument, "tens of millions" of people have used Inhance's containers each year for the past forty years. Id. at 47. And yet none of the Intervenors allege any actual harm from exposure, nor can they point to anyone else who has actually experienced any adverse health effect. That lack of evidence should be telling. In Winter, it certainly was: There, the Supreme Court held that it was "pertinent" to

their denial of injunctive relief "that this is not a case in which the defendant is conducting a new type of activity with completely unknown effects on the environment," but rather had been engaging in the same practice for forty years with no documented consequences. *Winter*, 555 U.S. at 23.

Intervenors have similarly failed to show any environmental injury as a result of Inhance's challenged conduct. Once again, there is no evidence about the actual amounts, if any, of PFAS that are produced by Inhance's fluorination technology. There is no evidence about which PFAS may or may not be produced. There is no evidence about the exposure of the public to those PFAS, if they are created, or if that exposure may result in unreasonable risks of harm to the environment or human health. That is understandable: These questions are precisely the ones that EPA's risk assessment process under TSCA is designed to answer. See 15 U.S.C. § 2604(a)(3)(A)–(C). And critically, EPA has not yet reached a decision on those questions, or determined whether any regulatory action might be necessary. The significant overlap between the issues under the agency's consideration and Intervenors' request for injunctive relief is yet another reason for this Court to refuse an injunction at this early stage. See Monsanto Co. v. Geerston Seed Farms, 561 U.S. 139, 163 (2010) (given other forms of relief available to the agency, "the risk of [harm to plaintiffs] could be virtually nonexistent").

Aside from making a summary judgment motion premature, this lack of evidence renders inapposite Intervenors' reliance on case law where defendants did not dispute the substantial evidence that their practices very likely caused harms to the environment. *See United States v. Gear Box Z Inc.*, 526 F. Supp. 3d 522, 526 (D. Ariz. 2021) (defendant did not "explicitly address or refute th[e] evidence" that its products were "defeat devices" used to evade Clean Air Act emissions standards); *cf. Natural Res. Def. Council v. Southwest Marine, Inc.*, 236 F.3d 985, 1001

(9th Cir. 2000) (granting injunction under Clean Water Act only after "hear[ing] testimony . . . about the extreme degree of environmental degradation" caused by defendant's actions and after "allow[ing] further argument and evidence" to be entered on appropriateness of injunctive relief).

In fact, a district court has already denied Intervenor PEER a preliminary injunction in very similar circumstances, on the basis that the plaintiffs had identified only speculative risks of harm, and the burden on defendants outweighed any benefits of enjoining their conduct and requiring remediation efforts. In that case, "[p]laintiffs assert[ed] that they will suffer irreparable harm if the Court does not grant their requested injunctive relief because each day the students and teachers at the school are exposed to the PCB-containing caulk increases the risk that they will suffer the serious health consequences associated with exposure to PCBs." *America Unites For Kids*, 2015 WL 2352184 at *4.³

The district court disagreed: "[T]he Court does not believe that the speculative risk identified by Plaintiffs justifies granting the preliminary injunctive relief they seek." *Id.* at *5. The district court reached this conclusion despite finding that plaintiffs were likely to succeed on the merits of their claim that those defendants had violated TSCA. *Id.* at *6. In particular, "[t]he balance of hardships, which in this instance involves weighing the minimal harm from exposure to PCBs in an environment where the District has management practices" to reduce exposure "against the disarray that would be caused by . . . requiring complicated remediation efforts on short notice, does not support issuance of preliminary injunctive relief." *Id.* at *5. *See also State of New York v. Nuclear Regul. Comm'n*, 550 F.2d 745, 756-757 (2d Cir. 1977) (speculative harm about risk of public exposure to plutonium via airline transport of the material not sufficient to warrant entry of injunction). So too here. Intervenors have pointed to no facts that raise their

³ The district court later dismissed PEER from the lawsuit for lack of standing. *America Unites for Kids v. Lyon*, No. CV 15–2124, 2018 WL 11342015, at *1 (C.D. Cal. Dec. 20, 2018).

speculative concerns about possible exposure to LCPFACs to the level of irreparable harm required for the "extraordinary" remedy of injunctive relief.

The remaining two factors of the *Winter* test also weigh strongly against the issuance of an injunction. Enjoining Inhance's business practices would significantly harm Inhance, the national economy, and the public interest.

Fluorination of plastic containers increases the barrier properties of those containers. This prevents the contents of those containers—which, as Intervenors themselves have documented, are often pesticides, fertilizers, organic solvents, or other petroleum products—from leaching out into the environment. In fact, certain chemicals and solvents can only be stored in barrier-protected plastic, glass, or metal containers, as they are the only types of materials capable of withstanding those chemicals' corrosive effects. Plastic is by far the most cost-effective and practical material of the three. For this reason, barrier protection processes such as fluorination play a critical role in protecting the public from exposure to known hazardous materials.

Enjoining Inhance's fluorination technology would be massively disruptive to both the company and the national economy. Inhance itself is classified as a small business that employs 333 individuals across the United States. Iyer Decl. ¶ 8. Inhance would be effectively shuttered if it were unable to treat fluorinated containers, resulting in the vast majority of those employees losing their jobs. Iyer Decl. ¶ 17. This kind of devastating financial loss has been recognized as irreparable harm, and weighs strongly against granting Intervenor-Plaintiffs' requested relief in this case. *Minard Run Oil Co. v. United States Forest Serv.*, 670 F.3d 236, 255 (3d Cir. 2011) (enjoining government action where it would "dramatically affect[] [appellees'] business and would probably cause them to shut down or go bankrupt if continued"); *South Camden Citizens In Action v. New Jersey EPA*, No. 01-2224, 2001 WL 34131402, at *1 (3d Cir. June 15, 2001) ("[T]he

loss that the appellant will suffer as a result of its inability to operate its facility pending appeal cannot be compensated for by a money judgment.").

The negative consequences of Intervenors' requested relief would stretch much further: Inhance provides fluorination services for approximately 120 million containers and other articles annually to a number of major industries in the United States including the medical supply chain, crop protection, industrial chemical, automotive, and water craft manufacturing industries. Iyer Decl. ¶ 17. Inhance's supply of these containers and articles is a critical portion of these customers' inventory and needs; for many customers, the entirety of their barrier needs is satisfied by Inhance's fluorination technology. Iyer Decl. ¶¶ 17–18. If Inhance were unable to supply containers to those industries, the resultant supply chain bottleneck would significantly derail the national economy. See Clean Ocean Action v. York, 57 F.3d 328, 330 (3d Cir. 1995) ("catastrophic injuries to the shipping industry" that would be caused by injunction "outweighed the minimal or non-existent injuries to plaintiffs" even though defendants had likely violated ocean dumping regulations).

Importantly, Inhance provides fluorinated fuel tanks and fuel systems to the original equipment manufacturers (OEMs) of marine and off-road equipment. Such fuel tanks and systems are certified by EPA and the State of California to meet strict evaporative emissions standards required by the Clean Air Act's ambient air quality program, which is designed to achieve and maintain air quality. For many of these OEM applications, there is no substitute fuel tanks and fuel systems that are certified to meet clean air standards. Identifying and certifying substitute fuel tanks and fuel systems would take months if not years. The negative consequences of such would severely impact these industries and air quality. It would likewise take many months, if not years, to build a sufficient alternative capacity to fulfill customers' needs for containers that have the

same barrier protection attributes as those offered by Inhance. Furthermore, Inhance's investments in additional research and development efforts, many of which are geared towards improving the safety and longevity of plastic-stored products, would be permanently shuttered.

Finally, Intervenors' request that Inhance inform "all prior recipients of fluorinated containers" that the fluorination technology violates TSCA—which, again, is subject to serious doubt—would place unnecessary economic burdens on Inhance and would significantly and adversely affect the company's goodwill. Intervenors' Proposed Order 2. As a preliminary matter, Intervenors do not have standing to bring this claim, *see supra* at 6–18. Even if they did, however, it would be vastly more burdensome than beneficial. If, as is likely, Inhance prevails on the merits, then the company would have to rescind these notifications, which would add confusion and uncertainty to the marketplace, and further unduly erode the company's reputation.

CONCLUSION

For the foregoing reasons, as well as those in Inhance's brief in opposition to the Government's motion for summary judgment and the supporting exhibits referenced therein, Intervenors' motion for summary judgment should be denied.

Respectfully submitted,

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